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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,406	09/01/2000	Jennifer L. West	RICE 100	7133

7590

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/653,406

**Applicant(s)**

WEST ET AL.

**Examiner**

Blessing M. Fubara

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18 and 20-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1615

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114 and letter, all filed 09/02/04. Claims 18 and 20-24 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 09/02/04 has been entered.

In the request for continued examination, applicants instructed consideration of amendment filed August 13, 2004. However, the record does not show amendment that was filed 08/13/04. Amendment filed 05/24/04 is the last amendment on record. That amendment and remarks will be considered on the merit.

Applicants' argument with respect to Roth et al. (US 5,879,713) and Trescony et al. (US 5,994,444) is persuasive since in both prior art references the biologically active agents are entrapped in the polymer.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1615

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic and diagnostic agent, does not reasonably provide enablement for preventative or prophylactic agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Preventative agent or prophylactic agent is not specifically defined as to the type of agent that is used as prophylactic or preventative agent and what that agent is preventing. Since there is no exemplification of what is prevented or what drug is used for the prophylaxis, the specification does not provide guidance on how to perform the prophylaxis, what drug(s) is/are involved in the prophylaxis and the data to support prophylaxis or preventing.

5. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is vague and indefinite because it is not clear where “adhere tissue, ‘provide support or coat the tissue,” recited in line 2 of the claim fit in the claim.

#### ***Double Patenting***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 20-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-25 of copending Application No. 10/129418. Although the conflicting claims are not identical, they are not

Art Unit: 1615

patentably distinct from each other because both applications are drawn method of treatment comprising administering macromer composition comprising nitric oxide (NO).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants indicate in the remarks of 09/02/04 that any double patenting issues will be addressed when allowable subject is found. The rejection is thus made again since the co-pending application is still pending and since no terminal disclaimer is provided.

Other Matters:

It appears that "stint" in claim 24 should really be ---stent---.

The instant claims are directed to method for controlled release of therapeutic or diagnostic agents and the method comprises administering to a tissue in need thereof, a biocompatible, polymerizable macromer composition that comprises at least one nitric oxide (NO) carrying region...and wherein the NO or the NO modulating compound is released from the macromer composition following in situ polymerization.... Based on the method where the composition polymerizes in situ to release the NO or the NO modulating compound, the following art of interest is noted.

Smith et al. (WO 96/32136, cited on PTO Form 1449) discloses that a polymer bound nitric oxide/nucleophile adduct composition can be applied with specificity to a biological site of interest and the site specific application of the polymer bound adduct composition enhances the selectivity of the action of the nitric oxide releasing  $N_2O_2^-$  functional group (page 7, lines 19-35). The nitric oxide is bound to the polymer physically or chemically (page 6, lines 22-30). The

Art Unit: 1615

composition of Smith is not a prepolymer that would polymerize in situ to release NO under physiological conditions.

Diodati et al. ("Complexes of Nitric Oxide with Nucleophiles as Agents for the Controlled Biological Release of Nitric Oxide: Hemodynamic Effect in the Rabbit," in *Journal of Cardiovascular Pharmacology*, 22:287-292, cited on PTO Form 1449) discloses the hemodynamic effect of Nitric Oxide/Nucleophile complexes. These complexes do not polymerize in situ to release NO.

Saavedra et al. (US 5,632,981) discloses nitric oxide/nucleophile complexes that are capable of releasing nitric oxide under physiological conditions and the complex comprises peptide, polypeptide, protein or nucleic acid, to which is bound nitric acid releasing compound (abstract; column 3, lines 55-60; column 5, lines 55-60; column 6, lines 45-49). The complex of Saavedra does not polymerize in situ to release nitric oxide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Blessing Fubara  
Patent Examiner  
Tech. Center 1600

A handwritten signature in cursive script, appearing to read 'Blessing Fubara', written over the printed name.